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International application number: PCT/AU05/000248

International filing date: 24 February 2005 (24.02.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/547,812
Filing date: 25 February 2004 (25.02.2004)

Date of receipt at the International Bureau: 06 June 2005 (06.06.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

PA 1301292

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APPLICATION NUMBER: *60/547,812*
FILING DATE: *February 25, 2004*

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV 225385483 US

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☐ *Additional inventors are being named on the* 0 *separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

CARDIOGENIC MONITORING AND CONTROL IN PRESSURE TREATMENT OF SLEEP DISORDERED BREATHING

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ENCLOSED APPLICATION PARTS ***(check all that apply)***

☑ Specification *Number of Pages*	7	☐ CD(s), Number	
☑ Drawing(s) *Number of Sheets*	1	☑ Other (specify)	return itemized postcard
☐ Application Data Sheet. See 37 CFR 1.76			

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Respectfully submitted,

SIGNATURE _____ Date 2/25/2004

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USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

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CARDIOGENIC MONITORING AND CONTROL IN PRESSURE TREATMENT OF SLEEP DISORDERED BREATHING

This invention is a method and apparatus for detection and analysis of cardiac signals in patient airflow signals.

The invention also provides for a method of controlling a cardiac treatment device by use of cardiac signals in patient airflow signals.

This invention also provides a method for screening and diagnosing cardiac morbidity/condition by use of cardiac signals in patient airflow signals.

This invention also provides a method for screening and diagnosing cardiac and respiratory co-morbidities by use of patient airflow signals and cardiac signals in patient airflow signals.

It is known that as the heart pumps, the lungs are perfused with blood (as they have a lot of vascular structure), and the pressure waves in the blood pulse have an impact on the air flow. These pressure waves appear as cardiogenic oscillations detectable in measures of a patient's airflow.

ResMed nasal CPAP devices such as the AutoSet SPIRIT™ monitor patient airflow. The monitored airflow is used to generate an airflow signal. This monitoring is achieved by use of a flow sensor and sometimes a pressure transducer in fluid connection with the patient's airflow. Typically the fluid connection is achieved by tapping into some point of the air circuit, which delivers air from the flow generator via a gas conduit and patient interface to the patient's breathing passages.

Typically these airflow signals are used to monitor a patient breathing especially during sleep and are used in determining the status of the patient's breathing. For example, the airflow information is used by the ResMed device to determine the patient's airway patency. Information regarding airway patency can be used as part of the screening for sleep disordered breathing and to control a ventilatory assist device in providing nasal CPAP to stabilize the upper airway. Examples of such methods and apparatus are taught by US Patent No. 5,245,995 and US Patent No. 5,704,345 and US Patent No. 5,245,995 and US Patent No. 5,704,345 and US Patent No. 6,532,957 and

US Patent No. 6,575,163 and US Patent No. 6,484,719 and US Patent No. 6,688,307 and US Patent No. 6,532,959.

It is known that ResMed devices such as the AutoSet SPIRIT can generate a signal indicative of cardiogenic oscillation present in the airflow signal.

An example of a cardiac signal represented by oscillations are detected in the airflow signal is shown in Fig. 1.

Because of the interest in airflow the cardiogenic signal may be filtered out or otherwise ignored by the ventilatory assist device's control algorithms. An exception to this is where the detection or non-detection of cardiogenic oscillations is used by the control algorithms. As taught by US Patent No. 6,029,665 the monitoring for cardiogenic oscillations is relevant to the determination of the occurrence of central apnea. The entire disclosure of which is incorporated by reference.

In normal respiratory flow, the airway is open. Therefore cardiogenic oscillation is present during normal respiratory flow. During an apnea the airflow signal will reduce and this reduction will be identified by an apena detector. Once an apena is detected then it is possible to determine whether a closed apnea has occurred by looking at the airflow signal for the presence of cardiogenic oscillation. If there is no cardiogenic oscillation, then it may be determined that the apnea involves a closed apnea i.e. a closed airway. If cardiogenic oscillation is detected during an apena (i.e. during a period of no airflow) it may be concluded that the airway is open.

An apenaic event involving a closed air way may occur during both an apnea with accompanying respiratory effort as well as a central apnea (ie an apnea where there is no respiratory effort). However if there is another indicator of respiratory effort (eg information about breathing diagram movement collected from a holter monitor or information from a suprasternal notch movement detector as taught in US Patent No, 6,445,942 then it is possible to determine whether the closed airway is occurring during an apena involving respiratory effort or a central apena. The closed airway central apena occurs where there is no airflow and no detected respiratory effort).

Similarly if cardiogenic oscillation is detected during an apnea, then it may be concluded that the airway is open and the event is a central apnea.

The present invention uses the capacity to detect the presence of the cardiogenic oscillation in the airflow for the purpose of determining the occurrence and nature of cardiogenic events. Optionally, other detectors of cardiac related information (e.g. cardiac rate) such as a pulse oximeter may be utilized.

Preferably, the invention uses indicators of airflow and cardiogenic oscillations for example as described above.

Preferably the airflow signal is filtered so as to distinguish between the airflow and the cardiogenic oscillations.

Preferably the filtering presents a spectral difference between respiratory flow and cardiogenic flow. The filtering may be used to attenuate the respiratory component of the flow and isolate the cardiogenic component of the flow. As the cardiogenic part of the flow may be isolated, further processing may be applied to the cardiogenic signal. For example a threshold detection level may be applied to determine whether there is present cardiogenic oscillations above zero line or not.

A band filter may be applied to the airway flow signal so as to create a window on the cardiogenic events. A suitable band filter may keep signals of approximately 60 hz but reject signals of 30 hz or lower (i.e. reject those signals which are generally associated with respiration and physical movement of the patent) and reject signals higher than 60 hz (i.e. reject those signals which are generally associated with system noise rather than being representative of cardiogenic events). Experimentation will allow optimization of the band filter for a given implementation of the inventive method.

While the cardiogenic airflow may be detected during any portion of the patient's respiratory cycle or its intirety, preferably the detection of cardiogenic oscillation may occur at least during the mid- to end expiration portion of the patient's breath (because the best resolution of the cardiogenic oscillations occurs during this portion of the respiratory cycle). Where only this portion of the breath is used for monitoring cardiogenic oscillations the signal processing needed to achieve the requisite resolution is simplified. Indeed for some applications it may be sufficient for cardiogenic oscillation monitoring to occur only during that portion of the respiratory cycle i.e. it is sufficient to

monitor less than all the heart-beats per breath. Known techniques may be used to determine the relevant portion of the respiratory cycle from which the cardiognic oscillations are extracted. For example, the middle to end of the expiratory cycle may be detected by tracking the recent average lapsed time of prior expiratory cycles and using the time in conjunction with detecting the start of expiration, i.e. by comparing flow to a threshold to detect zero crossings. Alternatively, the continuous phase may be detected to isolate the later portion of the expiratory cycle as disclosed in US Patent No. 6,532,957, the disclosure of which is incorporated by reference.

Preferably the investigation of the presence and if present the frequency and amplitude of cardiogenic oscillations is identified at least during the occurrence of an open apnea. During the open apnea the cardiogenic oscillation signal should be observable over the period of several seconds without the complication of the concurrent existence of the airflow signal. During this time it is possible to have a very clear representation of the cardiogenic condition and perfomance as represented by the cardiogenic oscillation signal. Due to the known association between central apneas and cardiac morbidity observation at this time can be of important in the task of making a broader determination of patient condition and decisions regarding treatment. As previously discussed, the detection of any open central apnea may be determined by any known method, for example, by a method as disclosed in U.S. Patent no. 5,704,345, the disclosure of which is incorporated by cross reference.

By continuously or periodically measuring the occurrence of cardiogenic oscillations it is possible to monitor over an extended period a patient's changing cardiac condition. For example, an arrhythmia may be detected by determining an irregularity in the force or rhythm of the heartbeat signal from the cardiogenic oscillations by an apparatus configured or programmed to do so. Thus, the amplitude and/or frequency of the signal may be compared to thresholds representing expected or prior average heartbeat force and/or rhythm for the patient to determine if such deviates from a norm. Similarly other patterns indicative of arrhythmia or normal cardiac force/rhythm may be stored as templates and compared to the signal to detect the presence of arrhythmia or the absence of normal cardiac functioning. If such an arrhythmias is detected at some time during a monitoring period then an appropriate response may be initiated which may include any of:commencing arrhythmias treatment, sending a signal to the patient

or care provider or physician or recording the event for later observation. Such a facility is particularly useful in view of the known comorbidity involving cardiac conditions and respiratory disorders such a sleep disordered breathing.

As the present invention allows for the determination of cardiac timing from the cardiogenic oscillation signal it is possible to determine a number of heart-rate parameters such as average rate, variability, arrhythmia etc. This monitoring may be performed without the additional effort and expense of using concurrent pulse oximetry. All information regarding cardiac conditions may be observed in real time by way of suitable display, transmitted or recorded.

In one embodiment of the invention an apparatus may be configured or programmed to do the following while patient is wearing mask:

1/ Measure airflow

2/ Identify & isolate cardiogenic signal from airflow

3/ Calculate heart-rate from cardiogenic signal

4/ Look for abnormalities in heart-rate (arrhythmias)

5/ If an abnormality is detected, generate or tell someone (alarm/patient/physician/etc)

This can be done by and apparatus every night for the rest of the patient's life.

Other applications of the present invention include the following embodiments:

It has been observed that cardiac stroke volume affects the amplitude of cardiogenic oscillations. It is also known that CPAP treatment will affect stroke volume. Therefore by monitoring carcinogenic oscillations in accordance with the present invention it is possible to titrate CPAP treatment so as to influence and preferably to optimize cardiac stroke volume. This may be achieved without uninterrupted monitoring of heart-beats. Rather it may be achieved with the monitoring of only 1-2 heart-beats per breath i.e. by monitoring only during a portion of the respiratory cycle, preferably during the mid- to end expiration portion. For example, a target stroke volume may be monitored by examining amplitude of the cardiogenic oscillations and pressure treatment may be adjusted to servo-control the amplitude toward a desired target.

It has been proposed that pulse-transit time may serve as a non-invasive means of inferring respiratory effort and arousals. Pulse-transit time is traditionally measured

from the ECG QRS complex to the time of arrival at the finger utilizing pulse oxymeter. However this technique has the disadvantage that the pre-ejection period is included in the measured delay. The present invention allows for the achievement of a more accurate measure of pulse-transit time (i.e. a measure of pulse-transit time without the pre-ejection period component). By performing uninterrupted monitoring of cardiogenic oscillations concurrently with pulse oximetry, pulse-transit time may be estimated. An advantage of the present invention is that it uses cardiogenic oscillations as the measured cardiac timing. The cardiogenic oscillations relate to the heart's mechanical systolic event rather than the electrical systolic event, so the pre-ejection period isn't included.

The present invention also provides for the monitoring of cardiogenic oscillation information with ECG information. This information allows for the assessment of changes in the heart's pre-ejection period, which reflects the ability of the left ventricle to eject. Assessments of changes in the heart's pre-ejection period provides an indication of cardiac health, blood pressure, peripheral vascular resistance, and other cardio-circulatory conditions that are of interest to patient management..

The information gained from the repeated observation of cardiogenic oscillations (particularly cardiac cycle timing history) may be used to predict the next cardiac cycle and thereby allow for ventilatory support to be modified so as to assist cardiac function. For example CPAP therapy pressure may be dipped or peaked according to the cardiac cycle to assist right atrial filling (pressure dip), left ventricular ejection (pressure peak), cardiac perfusion (pressure peak at early diastole) etc.

As the present invention provides for an accurate measure of cardiogenic oscillations present in the airflow signal it provides information relevant for a control algorithm to better manage the inference such artifact signals impose on conventional ventilator triggering circuits (e.g. by better identifying and filtering out the signal attributable to cardiogenic oscillations). Of particular interest is the identification and filtering out of cardiogenic oscillation signals occurring near end-expiration (i.e. cardiogenic oscillation signals occurring at a part of the respiratory phase when it is desirable for the ventilator to most accurately cycle from expiration to inspiration in accordance with the applicable treatment algorithm).

While the invention has been described with various alternative embodiments and features, it is to be understood that the embodiments and features are merely illustrative of the principles of the invention. Those skilled in the art would understand that other variations can be made without departing with the spirit and scope of the invention.

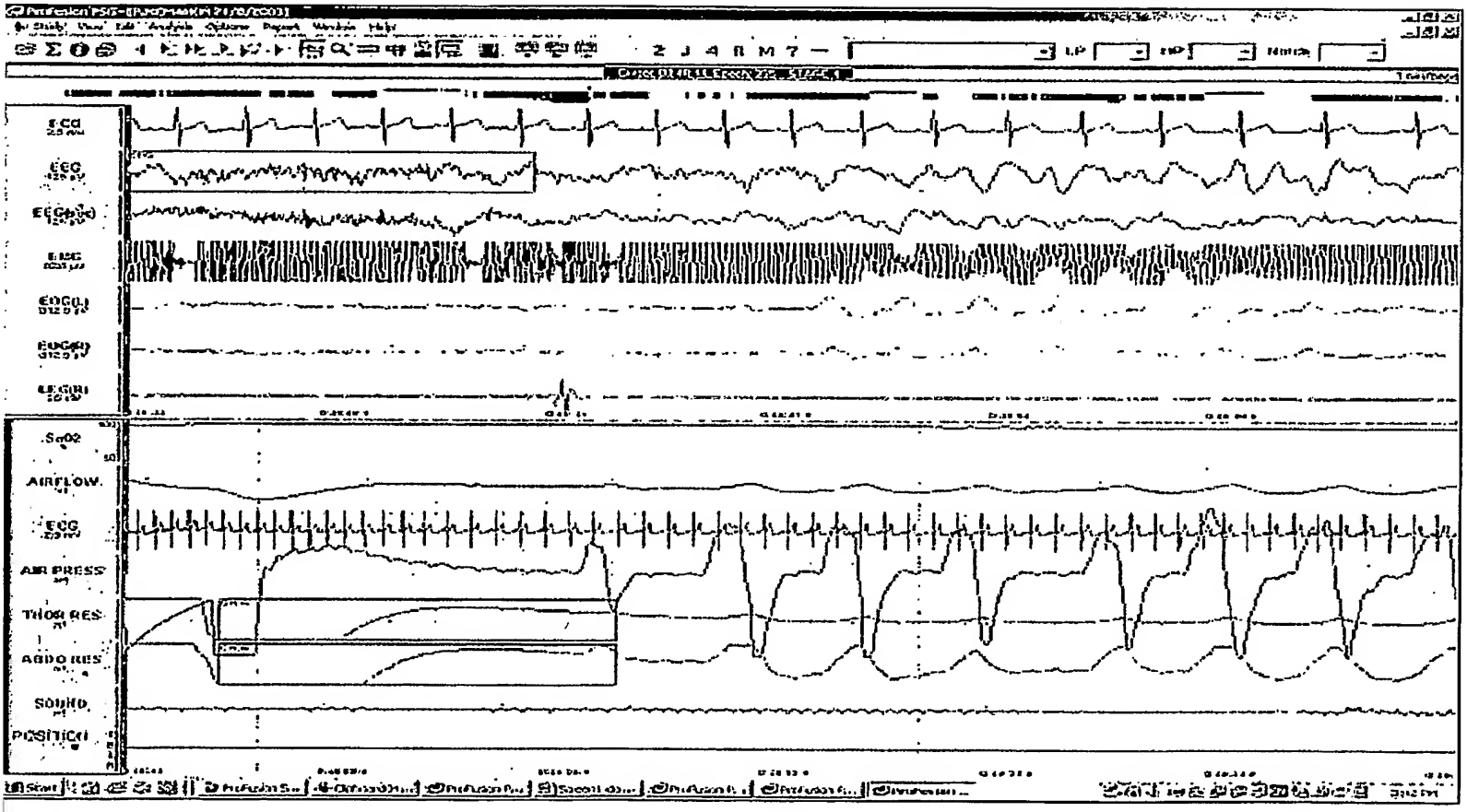

FIGURE 1

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